

### **REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 15-38 will be active in the application subsequent to entry of this Amendment.

Previous claims 13 and 14 have been withdrawn and new claims 35-38 presented defining various embodiments of the method of carrying out the present invention consisting of the recited steps. As a consequence, claims 13 and 14 have been withdrawn and, where appropriate, the dependencies of previous claims 15, 17, 19, 22, 25, 26, 29, 32-34 have been amended, where appropriate, to depend from one or more of these new claims.

The Official Action raises essentially two rejections. The first concerns the wording of previous claim 13 with regard to the transitional expression "consisting essentially of". This terminology is not employed in the new and amended claims now under consideration.

For the record, applicants are employing transitional phrases in the manner prescribed by MPEP §2111.03 "Transitional Phrases" a copy of which is attached for the examiner's convenience. Attention in particular is directed to the discussion of "consisting essentially of" as well as "consisting of" in the attached pages.

The remaining issue for consideration and resolution is the rejection of alleged anticipation of previous claims 13-34, or the "obviousness" of these claims over WO 98/48640 to Vaarala et al. The applied reference refers to "[s]uitable cation exchange resins include Amberlite C-20" *see* page 4, lines 19-20. The examiner will note that the term "Amberlite" is prefaced by the limiting term "cation exchange resins". The rejection advanced on page 3 of the Official Action is founded on the proposition that the term "Amberlite" by itself automatically and consistently refers to styrene-based adsorption resins. In fact, this is not the case – the reference applies it in very specific terms, as does the art - regrettably the Official Action does not.

The Examiner has stated that:

"It is notoriously well-known that the resin (Amberlite manufactured by Robin & Haas) utilized in Example 1 (page 8 of WO 98/48640) is a styrene based adsorption resin." Unfortunately, this statement is not correct for the reasons already established in the declaration made by Olli Tossavainen on May 23, 2003, of record.

The evidence of record and as attached to this response makes it clear that Robin & Haas manufactures different types of resins under the trademark Amberlite. This has been already discussed in detail in the declaration filed by the applicant.

For further evidence see the attached print from the Rohm & Haas web-site (<http://www.rohmhaas.com/ionexchange/nutrition/products.htm>), where it reads:

"Rohm and Haas has taken the most important ion exchange and adsorbent products and created a dedicated product line under the AMBERLITE™ FP name."

While it is true that the trade names and trademarks have been changed during the years, it does not change the fact that ion exchange resins differ essentially from adsorption resins.

Suitable strong cations exchange resins used in WO 98/48640 include Amberlite C-20, Spherosil 5, Amberlite IR-120 and Finex VO 7. Please see the attached table containing properties of strong cation exchange resins manufactured by Rohm & Haas. This table also contains the Amberlite IR-120 resin.

Suitable macroporous adsorption resins used in this patent application include Dowex XUS 40285.00 and Amberlite XAD 7. Please also see attached table containing typical properties of Amberlite polymeric absorbents. This table also contains the Amberlite XAD-7 resin.

Thus, Amberlite C-20 and Amberlite IR-120 are strong cations exchange resins, whereas Amberlite XAD 7 is an adsorption resin. There should be no question about the fact that ion exchange resins differ essentially from adsorption resins and that the resins used by applicants are fundamentally different from those mentioned in the cited reference.

Further, the Examiner argues that the reference teaches a process for removing bovine insulin from a protein material using a resin treatment combined with a filtration treatment as is claimed. This is not an accurate representation of the reference. All Amberlite® resins are not the same nor are they completely interchangeable.

The reference discloses a method of preparing a substantially insulin-free protein composition, wherein the method comprises the steps of: a) treating the liquid fat-free protein-containing material originating from cow's milk with a strong cation exchange resin, b) concentrating the liquid fat-free protein-containing material obtained in step a) by ultra and dia-filtration, and evaporation of the obtained protein concentrate, and optional steps c) to e).

However, there is no mention in the applied reference (or elsewhere in this art) about combining at least one ultra and dia-filtration treatment with adsorption resin treatment to remove bovine insulin from a liquid fat-free proteinous material originating from cow's milk.

The method disclosed in the reference optionally includes step d) where the protein hydrolysate obtained in optional step c) is passed to hydrophobic chromatographic treatment. This chromatographic treatment is used for the removal of hydrophobic peptides and therewith possible bovine insulin hydrolysis products from the hydrolysate (page 7, lines 24 to 28). These hydrophobic peptides and bovine insulin hydrolysis products are substantially smaller molecules than the bovine insulin molecule. This chromatographic treatment can be carried out using a hydrophobic adsorption resin or activated charcoal (reference: page 7, lines 29 to 32). According to Vaarala (page 8, lines 1 to 4), the amino acid composition of the product changes due to this treatment and thus small amounts of phenylalanine and tyrosine has to be added during the production of nutritive preparations. By contrast, the method of the present invention does not substantially alter the taste of the product (page 1, lines 13 to 17), and thus, there is no need for addition of such amino acids during the production of nutritive preparations. The possibility of such additions is excluded by the language of new claims 35-38.

Further, the mechanism of the treatment with a strong cation exchange resin as in the reference is completely different from the mechanism of the treatment with adsorption resin as claimed in the present invention.


In the present application Amberlite XAD 7 is utilized in Examples 3, 5, 6 and 7. Amberlite XAD 7 is a polymeric adsorbent, i.e. an adsorption resin. These polymeric adsorbents are unique products for the purification recovery of products from fermentation in the bioprocessing/nutraceutical industry. Polymeric adsorbents are highly porous structures whose internal surfaces can adsorb and then desorb a wide variety of different species depending on the environment in which they are used. Polymeric adsorbents are non ionic adsorbents with high surface area.

In the method of the claims of the present application there is no mention of the use of a strong cation exchange resin, which is required in the method disclosed in Vaarala.

For the above reasons it is respectfully submitted that applicants' claims define inventive subject matter. Reconsideration and favorable action are solicited.

Respectfully submitted,

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# **Manual of PATENT EXAMINING PROCEDURE**

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claim limitation”); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim); *STX LLC v. Brine*, 211 F.3d 588, 591, 54 USPQ2d 1347, 1350 (Fed. Cir. 2000) (holding that the preamble phrase “which provides improved playing and handling characteristics” in a claim drawn to a head for a lacrosse stick was not a claim limitation). >Compare *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002) (A claim at issue was directed to a method of preparing a food rich in glucosinolates wherein cruciferous sprouts are harvested prior to the 2-leaf stage. The court held that the preamble phrase “rich in glucosinolates” helps define the claimed invention, as evidenced by the specification and prosecution history, and thus is a limitation of the claim (although the claim was anticipated by prior art that produced sprouts inherently “rich in glucosinolates”).)<

During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of no significance to the structure and process of making.); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim did not distinguish over the prior art apparatus). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (anticipation rejection affirmed based on Board’s factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant’s claim 1 (a dispensing top for dispensing popcorn in a specified

manner)) and cases cited therein. See also MPEP § 2112 - § 2112.02.

### 2111.03 Transitional Phrases

The transitional phrases “comprising”, “consisting essentially of” and “consisting of” define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.

The transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“comprising” leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”).

The transitional phrase “consisting of” excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“consisting of” defined as “closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith.”). A claim which depends from a claim which “consists of” the recited elements or steps cannot add an element or step. When the phrase “consists of” appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause; other elements are not excluded from the claim as a whole. *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 230 USPQ 45 (Fed. Cir. 1986).

The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in origi-

nal) (Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). "A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also *Atlas Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama-Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although 'consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing

intrinsicly wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language.").

## OTHER TRANSITIONAL PHRASES

Transitional phrases such as "having" must be interpreted in light of the specification to determine whether open or closed claim language is intended. See, e.g., *Lampi Corp. v. American Power Products Inc.*, 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1453 (Fed. Cir. 2000) (The term "having" was interpreted as open terminology, allowing the inclusion of other components in addition to those recited); *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l Inc.*, 246 F.3d 1336, 1348, 57 USPQ2d 1953, 1959 (Fed. Cir. 2001) (term "having" in transitional phrase "does not create a presumption that the body of the claim is open"); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997) (In the context of a cDNA having a sequence coding for human PI, the term "having" still permitted inclusion of other moieties.). The transitional phrase "composed of" has been interpreted in the same manner as either "consisting of" or "consisting essentially of," depending on the facts of the particular case. See *AFG Industries, Inc. v. Cardinal IG Company*, 239 F.3d 1239, 1245, 57 USPQ2d 1776, 1780-81 (Fed. Cir. 2001) (based on specification and other evidence, "composed of" interpreted in same manner as "consisting essentially of"); *In re Bertsch*, 132 F.2d 1014, 1019-20, 56 USPQ 379, 384 (CCPA 1942) ("Composed of" interpreted in same manner as "consisting of"; however, court further remarked that "the words 'composed of' may under certain circumstances be given, in patent law, a broader meaning than 'consisting of.'").

## 2112 Requirements of Rejection Based on Inherency; Burden of Proof

The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection





Ion Exchange Resins - Nutrition

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The Amberlite™ FP Range for Food Purification

In order to respond more effectively to the needs of the Nutrition market in terms of regulatory requirements, Rohm and Haas has taken the most important ion exchange and adsorbent products and created a dedicated product line under the AMBERLITE™ FP name.

Rohm and Haas has maintained the product quality and performance of these traditional products but has added specific information on the Regulatory Status and pre-treatment associated with each of the AMBERLITE™ FP products in order to facilitate the acceptance and continued use of these products within the Nutrition area.

New information and products will be added to the AMBERLITE™ FP product line over the coming months.

AMBERLITE™	Matrix	Ionic form	Water content (%)	Total Cap (eq/L) <sup>1</sup>	Remarks
Strong Acid Cations					
FPC11 Na	Gel Styrene-DVB	Na	43-47	2.12	High capacity and high mechanical and osmotic stability.
FPC14 Na	Gel Styrene-DVB	Na	41-49	2.08	High capacity. Decalcification of thin saccharose juices in all processes.

FPC21 H	MR <sup>2</sup> Styrene-DVB	H	52-57	1.76	Excellent mechanical and osmotic resistance. Good resistance to oxidation.
FPC22 Na <sup>3</sup>	MR Styrene-DVB	Na	47-54	1.88	Excellent mechanical and osmotic resistance. Demineralisation of dextrose solutions, removal of cationic species, amino acids and proteins (H <sup>+</sup> form); decalcification (Na <sup>+</sup> form).
FPC23 H	MR Styrene-DVB	H	44-53	2.23	Excellent mechanical and osmotic resistance, very high capacity. Quentín Process.
<b>Chromatographic Resins</b>					
CR1310 Na	Gel Styrene-DVB	Na	53-59	1.59	Very low uniformity coefficient and smaller harmonic mean size, low crosslinking.
CR1310 Ca	Gel Styrene-DVB	Ca	61-65 (H)	1.59 (Na)	Separation of sugars, polyols, etc. with high recovery and purity rates, fine HMS.
CR1320 Ca	Gel Styrene-DVB	Ca	58-64 (H)	1.63 (H)	Separation of sugars (fructose-glucose) in all types of designs.
CR1320 K	Gel Styrene-DVB	K	58-64 (H)	1.63 (H)	Suitable for exclusion process (molasses, betaine recovery) in all types of designs (SMB).
<b>Weak Base Anions</b>					
FPA51	MR Styrene-DVB	FB	54-60	1.50	High mechanical and osmotic stability, resistant to oxidation. Delonisation of concentrated sugar syrups, low isomerisation during deacidification.
FPA53	Gel Acrylic-DVB	FB	56-67	1.64	High basicity, excellent resistance to organic fouling. Delonisation of many organic solutions (citric acid, whey, gelatine, lactic acid). No isomerisation during deacidification of glucose.
FPA54	Formphenolic	FB	60-65	1.90	Very porous, hydrophilic phenolic structure, granular form, very good adsorption properties. Low swelling and excellent osmotic stability. Also suitable as enzyme carrier.
FPA55	Gel Acrylic-DVB	FB	56-64	1.60	Excellent osmotic and mechanical stability due to the flexibility of the acrylic matrix. Delonisation of many organic solutions (citric acid, whey, gelatine, lactic acid). Good rinsing properties.
<b>Strong Base Anions</b>					

FPA40 Cl	Gel Styrene-DVB	Cl	57-68	1.00	Highly porous gel type strong base resins for decolourisation of organic aqueous solutions.
FPA90 Cl <sup>3</sup>	MR Styrene-DVB	Cl	58-64	1.14	Good adsorption and elution of organic matters. High decolourisation efficiency.
FPA91 Cl	MR Styrene-DVB	Cl	54-61	1.10	Organic removal, good regeneration efficiency. Mixed bed polishing of glucose, fructose solutions.
FPA97 Cl	MR Styrene-DVB	Cl	50-56	1.24	High capacity type 2 strong base resin for colour removal or polishing applications.
FPA98 Cl	Acrylic-DVB	Cl	66-72	0.80	Good adsorption and elution of organic matters for highly coloured feedstock. Decolorisation of highly coloured juices.
<b>Adsorbents</b>					
<b>AMBERLITE™</b>	<b>Type/Matrix</b>	<b>Surface Area (m<sup>2</sup>/g)</b>	<b>Porosity (ml/ml)</b>	<b>Pore (Å)</b>	<b>Remarks</b>
XAD™16 HP	Aromatic	800	0.55	200-250	High purity non ionic adsorbent, high surface area, fruit juice upgrading.
Notes : <sup>1</sup> Typical value - <sup>2</sup> MR : macroreticular - <sup>3</sup> RF grade also available for reverse flow operation.					

[Back to top](#)

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Table XVIII

TYPICAL PROPERTIES OF AMBERLITE POLYMERIC ADSORBENTS

	Chemical Nature	Porosity Volume %	True Wet Density grams/cc	Area m <sup>2</sup> /gram	Average Pore Dia. Angstroms	Skeletal Density grams/cc	Nominal Mesh Sizes
XAD-1	Polystyrene	37	1.02	100	200	1.07	20 to 50
XAD-2	Polystyrene	42	1.02	330	90	1.07	20 to 50
XAD-4	Polystyrene	51	1.02	750	50	1.08	20 to 50
XAD-7	Acrylic Ester	55	Intermediate Polarity	450	80	1.24	20 to 50
XAD-8	Acrylic Ester	52					
XAD-9	Sulfoxide	45	1.09	140	250	1.23	25 to 50
XAD-11	Amide	41	1.14	250	80	1.26	20 to 50
XAD-12	Very Polar	45	1.07	170	210	1.18	16 to 50
	Nitrogen-Oxygen Group		1.06	25	1300	1.17	20 to 50

XAD-2, XAD-4, XAD-7 and XAD-8 are available in commercial quantities  
Currently, BDH supplies the following from stock, and some properties of these are outlined below.

- 15088 Amberlite XAD-2
- 15243 Amberlite XAD-4
- 15244 Amberlite XAD-7

Table VI

CATION EXCHANGE RESINS, STRONGLY ACIDIC, ACTIVE GROUP:  $-\text{SO}_3^-$ 

Cross-linked polystyrene-divinylbenzene

Typical applications: Water softening and deionisation; separation of rare earths; separation of peptides and amino acids; inorganic separations; esterification; catalysis; wine stabilisation, etc.

Resin	Grade	Form supplied	Particle size mm	Moisture content %	Wet density (apparent) g per ml	Exchange capacity	Cross linking %	Max operating temp °C	pH range
55009 'Amberlite' IR-120 (Na)  55001 'Amberlite' IR-120 (H) Maximum Limits of Impurities Fe 0.005 % Cu + Ni 0.0025 % Heavy metals as Pb 0.0025 %	Standard	Na <sup>+</sup>	0.300-1.18	44-48	0.84	Wet: 1.9 meq/ml Dry: 5.0 meq/g	8	120	1-14
55171 'Cation Exchange Resin'	Chromatographic	Na <sup>+</sup>	0.150-0.300	44-48	1.29	Wet: 2.0 meq/ml Dry: 4.5 meq/g	8	140	1-14
55036 Dowex 50-X2 (Na)	Standard	Na <sup>+</sup>	0.300-0.850	45	0.85	Wet: 1.9 meq/ml	8	150	1-14
55037 'Dowex' 50W-X2 Dowex 50W has very similar properties to Dowex 50 but is nearly white in colour.	Standard	Na <sup>+</sup>							
55038 'Dowex' 50W-X2 (H)	Standard	H <sup>+</sup>	0.30-1.00	53	0.80	Wet: 1.7 meq/ml Dry: 4.8 meq/g	8	150	1-14
55161 'Dowex' 50W-X2 (H)	Standard	H <sup>+</sup>	0.150-0.30	53	0.80	Wet: 1.7 meq/ml Dry: 4.6 meq/g	8	150	1-14
55162 'Dowex' 50W-X2 (H)	Standard	H <sup>+</sup>	0.075-0.150	53	0.80	Wet: 1.7 meq/ml Dry: 4.8 meq/g	8	150	1-14
55163 'Dowex' 50W-X2 (H)	Standard	H <sup>+</sup>	0.04-0.075	53	0.80	Wet: 1.7 meq/ml Dry: 4.8 meq/g	8	150	1-14
55046 'Duo-lite' C225 (Na)	Standard	Na <sup>+</sup>	0.300-1.18	48-52	0.85	Wet: 2.0 meq/ml	8	120	1-14
55150 'Duo-lite' C255 (H) Similar to Duo-lite C225 but more highly crosslinked and tougher. Specially developed for mixed bed condensate polishing.	Standard	H <sup>+</sup>	0.500-1.18	45-49	0.85	Wet: 2.0 meq/ml	10	140	1-14
55151 'Duo-lite' C26C (H) A macroporous resin with a high degree of cross-linking. Resistant to mechanical and osmotic stress.	Standard	H <sup>+</sup>	0.300-1.18	41-47	0.80	Wet: 1.8 meq/ml		140	1-14
55065 SRC 9 55155 SRC 13 55075 SRC 16 55076 SRC 17 55077 SRC 18	Chromatographic	Na <sup>+</sup>	0.300-1.18 0.300-1.18 less than 0.075 0.0300-1.18 0.150-0.300	1.3-1.4 0.68-0.85 0.68-0.85 0.46-0.7 0.46-0.7		Dry: 4.5-5.0 meq/g	4 8 8 12 12	120	1-14